

EXHIBIT 1

PPE Specific ID: 0012841 | Rev:4
Labeling Supplement 28 Nov 2014
RMO #15506 Gynecare TVT54254
Device Release Level: 4. Production
GYNECARE TVT™

Tension-free Support
for Incontinence

GYNECARE TVT™
Tension-free Vaginal Tape

GYNECARE TVT™ Single Use Device
GYNECARE TVT™ Reusable Introducer
GYNECARE TVT™ Reusable Rigid Catheter Guide
GYNECARE TVT™ anordning til engangsbrug
GYNECARE TVT™ indfører til flergangsbrug
GYNECARE TVT™ stift guiding kateter til flergangsbrug
GYNECARE TVT™ hulpmiddel voor eenmalig gebruik
GYNECARE TVT™ herbruikbare introducer
GYNECARE TVT™ herbruikbare starre kathetervoerder
GYNECARE TVT™ -laite, kertakäyttöinen
GYNECARE TVT™ -sisäinjieä, kestäkäyttöinen
GYNECARE TVT™ -katetri johdain, kestäkäyttöinen, jäykkä
Dispositif GYNECARE TVT™ à usage unique
Introducteur réutilisable GYNECARE TVT™
Guide de sonde rigide réutilisable GYNECARE TVT™
GYNECARE TVT™ Einmal-Implantat
GYNECARE TVT™ wiederverwendbares Einführungsinstrument
GYNECARE TVT™ wiederverwendbare starre Katheterführung
Συσκευή μιας χρήσης GYNECARE TVT™
Επαναχρησιμοποιήσιμος εισαγωγέας GYNECARE TVT™
Επαναχρησιμοποιήσιμος άκαμπτος οδηγός καθετήρα
GYNECARE TVT™
Dispositivo monouso GYNECARE TVT™
Introductor reutilizable GYNECARE TVT™
Guia rígida reutilizable por catetere GYNECARE TVT™
Dispositivo de utilização única GYNECARE TVT™
Introdução reutilizável GYNECARE TVT™
Guia rígido do cateter reutilizável GYNECARE TVT™
Sistema para un solo uso GYNECARE TVT™
Introducción reutilizable GYNECARE TVT™
Guía de catéter rígido reutilizable GYNECARE TVT™
GYNECARE TVT™ produkt för engångsbruk
GYNECARE TVT™ återanvändbar införare
GYNECARE TVT™ återanvändbar stel kateterguide



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14 When the needle has reached the bladder, the physician will view the GYNECARE™ VI introducer from the needle. Before the implant is pulled into the bladder, the 18 French Foley catheter and the device are removed. 4 Production

- ## CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

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